UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 18-10568-RGS

DUSA PHARMACEUTICALS, INC.

v.

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH, BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG

MEMORANDUM AND ORDER ON
CLAIM CONSTRUCTION

March 14, 2019

STEARNS, D.J.

In this multifaceted intellectual property dispute, plaintiff DUSA Pharmaceuticals, Inc., accuses defendants Biofrontera Inc., Biofrontera Bioscience GMBH, Biofrontera Pharma GMBH, and Biofrontera AG (collectively Biofrontera) of patent infringement and misappropriation of trade secrets.[1] Before the court are the parties' briefs construing the disputed claim terms of the two asserted patents – U.S. Patents Nos. 8,216,289 (the

[1] Specifically, DUSA's Second Amended Complaint (Dkt #84) sets out seven claims: patent infringement (Counts I & II); trade secret misappropriation under the Defend Trade Secrets Act (Count III); trade secret misappropriation under Mass. Gen. Laws ch. 93, § 42 (Count IV); common-law misappropriation of confidential, proprietary, and trade secret information (Count V); tortious interference with contractual relations (Count VI); and deceptive and unfair trade practices under Mass. Gen. Laws ch. 93A (Count VII).

’289 patent) and 9,723,991 (the ’991 patent). The court heard argument pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), on March 12, 2019.

THE ASSERTED PATENTS

The ’289 and the ’991 patents are both entitled “Illuminator for Photodynamic Therapy,” and list as inventors Scott Lundahl, Rebecca Kozodoy, Ronald Carroll, and Elton Leppelmeier. The ’289 patent was issued on July 10, 2012, from an application dated December 16, 2010. The ’991 patent was issued on August 8, 2017, from an application dated May 20, 2014. The application for the ’991 patent is a continuation of the application for the ’289 patent, which is itself a continuation in a long line of applications dating back to 1998. The two patents share the same specification.

The asserted patents are directed to improvements in photodynamic treatment (PDT) technology.

> Photodynamic therapy or photochemotherapy is currently being proposed to treat several types of ailments in or near the skin or other tissues, such as those in a body cavity. For example, PDT is being proposed to treat different types of skin cancer and pre-cancerous conditions. In PDT, a patient is administered a photoactivatable agent or precursor of a photoactivatable agent[2] which accumulates in the tissue being diagnosed or treated. An

[2] A specific precursor of a photoactivatable agent identified in the patent is 5-aminolevulinic acid (ALA).

> area of the patient which includes the tissue being diagnosed or treated is then exposed to visible light. The visible light causes chemical and/or biological changes in the photoactivatable agent which in turn selectively locate, destroy or alter the target tissue while at the same time causing only mild and reversible damage to other tissues in the treatment area.

'289 patent, col. 1, ll. 36-50. "For therapeutic reasons it is desirable to have a power output which is uniform in intensity and color. In particular, it is highly desirable to have an illuminator with a spectral output that overlaps to a large extent with the optical activation spectrum of the target photosensitizer." *Id.*, col. 2, ll. 24-28. However, "[c]onventional illuminators do not produce visible light that is sufficiently uniform in intensity over a contoured surface." *Id.*, col. 2., ll. 37-38.

Objectives of the asserted patents include:

- to provide an improved illuminator for PDT and/or PD [(photodiagnosis)];
- to provide an illuminator for PDT that produces visible light of consistent uniformity in terms of both spectral characteristics and intensity over a diversely contoured surface;
- to provide an illuminator for PDT or PD which produces visible light almost entirely in a selected wavelength range;
- to provide an illuminator for irradiating the face or scalp of a patient;
- to provide a cooling system for improving the irradiance uniformity of an illuminator;

- to provide an illuminator comprising a finite emitter that approximates the uniform output of an infinite plane emitter by varying the spacing of individual light sources within the illuminator; and

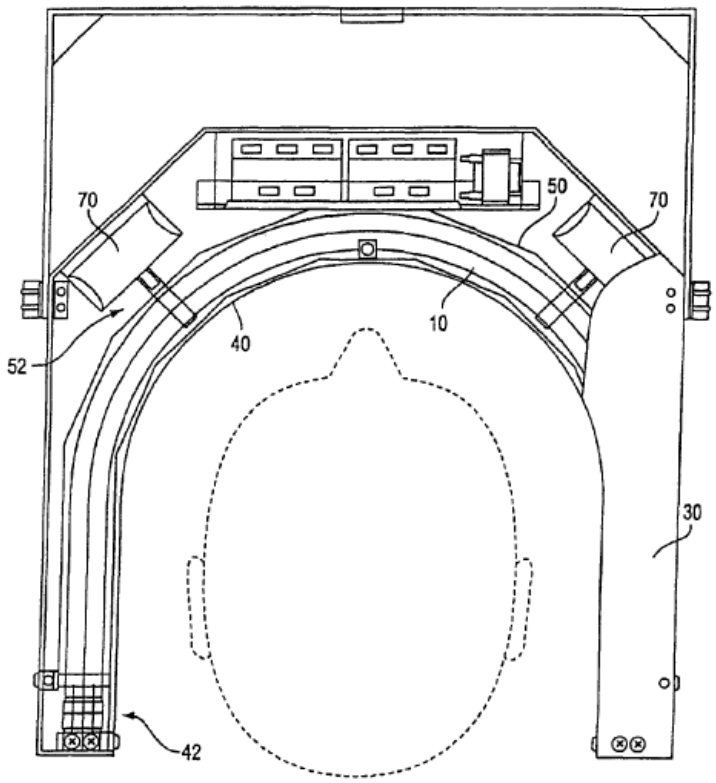
- to provide a monitoring system for an illuminator comprising a single visible light sensor monitoring the visible light output of a plurality of light sources and outputting a signal to adjust the visible light output from the plurality [of] light sources.

Id., col. 2, ll. 42-65. To accomplish the stated goals, the patents disclose

> [a]n apparatus and method for photodynamic therapy or photodynamic diagnosis using an illuminator comprising a plurality of light sources generally conforming to a contoured surface and irradiating the contoured surface with substantially uniform intensity visible light. The light sources may comprise generally U-shaped fluorescent tubes that are driven by electronic ballasts. Adjustment of the ballast voltage controls the output power of the tubes. The tubes are supported by a sheet-metal or plastic housing and are covered by a polycarbonate shield which directs cooling airflow within the unit and prevents glass-patient contact in the vent of tube breakage. An aluminum reflector located behind the tubes increases both the output irradiance and the uniformity of the output distribution. The spacing of the U-shaped tubes is varied to increase the output at the edges of the illuminator to make the output more uniform. Also, different portions of the tubes are cooled at different amounts, to improve uniformity. A light sensor monitors output from the U-shaped tubes to provide a signal for adjusting the output from the tubes.

Id., Abstract. Figure 1, reproduced *infra*, illustrates an exemplar of the illuminator described in the asserted patents.

FIG. 1



> According to one preferred embodiment illustrated in FIGS. 1-8, seven U-shaped fluorescent tubes 10(1)-10(7) are driven by three electronic ballasts 20. Adjusting the ballast voltage controls the output power of the tubes. The tubes 10(1)-10(7) are supported by a housing 30 and are covered by a polycarbonate shield 40 which directs cooling airflow within the unit and prevents glass-patient contact in the event of tube breakage. An aluminum reflector 50 located behind the tubes increases both the output irradiance and the uniformity of the output distribution.

Id., col. 5, ll. 27-36.

The ’289 patent sets out 19 method claims, while the ’991 patent sets out 12 appratus claims. For each patent, claim 1 is the only independent claim and is representative.

’991 patent claim 1. An illuminator for diagnosing or treating a patient, comprising:

> a plurality of light sources configurable in a spaced relationship to a patient to treat or diagnose a dermatological condition,
>
> a controller, connected to the plurality of light sources, to control the light sources,
>
> wherein the light sources are configured and controlled to provide a uniform output of light to the patient to treat or diagnose a dermatological condition,
>
> the light sources being configured and controlled such that uniform output of light is provided when measured at distances of 2’’ and 4’’.

’289 patent claim 1. A method of photodynamically diagnosing or treating a patient, comprising:

> illuminating the patient with an illuminator whose measured output over an active emitting area is at least 60% of the measured maximum over all operation distances.

The parties’ *Markman* briefs join on essentially two issues – whether an illuminator as contemplated by the asserted patents must necessarily conform to a contoured surface, and whether the claim terms “all operation distances” and “uniform output of light” are sufficiently definite to satisfy the standard set out by the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014).

DISCUSSION

Claim construction is an issue of law. *See Markman*, 517 U.S. at 388-389. Claim terms are generally given the ordinary and customary meaning that would be ascribed by a person of ordinary skill in the art in question at the time of the invention.[3] *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (en banc). In ascertaining how a person of ordinary

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[3] Despite differing formulations, the parties concur that the level of ordinary skill in the art is one of high sophistication. According to DUSA,

> a person of ordinary skill in the art at the time of the invention would have at least a Bachelor of Science degree in physics or bioengineering (or equivalent experience) and at least 3 years of experience related to PDT and/or other light-based therapies (or equivalent) using non-laser light sources. This person may have also worked in collaboration with other scientists and/or clinicians who have had experience developing or administering to patients PDT and/or other light-based therapies.

DUSA Br. (Dkt #72). Biofrontera, in turn, defines a person of ordinary skill in the art (POSITA) as one having

> at least a Bachelor of Science in electrical engineering, physics, biomedical engineering, computer engineering, material science, or a related scientific or engineering field, and at least one year of work or research experience in optics, optoelectronics, radiometry, photometry, or a related field. Alternatively, a POSITA in the relevant time frame would have been someone with at least four years of industry or academic experience in optics, optoelectronics, radiometry, photometry, or a related field.

Biofrontera Br. (Dkt #71) at 20 n.7.

skill in the art would have understood the claim terms, the court looks to the specification of the patent, its prosecution history, and, where appropriate, extrinsic evidence such as dictionaries, treatises, or expert testimony. *Id*. at 1315-1317. Ultimately, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316 (citation omitted).

"*illuminator*"

Biofrontera contends that an "illuminator" is "one or more light sources generally conforming to a contoured surface."[4] While agreeing that an illuminator is "a light emitting medical instrument," DUSA objects to Biofrontera's attempt to limit the term by confining it to contoured surfaces. Where, as here, Biofrontera maintains that the asserted patents disavow flat specimens as fitting within the ordinary meaning of illuminator, the standard of proof is "exacting."[5] *GE Lighting Sols., LLC v. AgiLight, Inc.*,

[4] Although the term "illuminator" appears only in the preamble to claim 1 of the '991 patent, Biofrontera asserts that it serves as a limitation for the claim, or in the alternative, that the term "plurality of light sources configurable in a spaced relationship to the patient" should be similarly construed as "plurality of light sources generally conforming to a contoured surface."

[5] There is no suggestion here that the patentees acted as their own lexicographer with respect to "illuminator."

750 F.3d 1304, 1309 (Fed. Cir. 2014). "[D]isavowal requires that 'the specification [or prosecution history] make[] clear that the invention does not include a particular feature.'" *Id.*, quoting *SciMed Life Sys. Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) (alterations in *GE Lighting*).

Biofrontera contends that a contoured shape is an essential component of the patented invention. The problem sought to be solved by the patents, as Biofrontera understands it, is that "[c]onventional illuminators do not produce visible light that is sufficiently uniform in intensity over a contoured surface," '289 patent, col. 2, ll. 37-38, particularly over a patient's face or scalp.

> The inverse square law of optics states that the intensity of light from a point source received by an object is inversely proportional to the square of the distance from the source. Because of this behavior, distance from the source is an important variable in all optical systems. Thus, in order to achieve uniform facial or scalp irradiation, variations in output irradiance with distance must be minimized.

Id., col. 4, ll. 29-35. To minimize the distance to the patient, the patents disclose "[a]n apparatus and method for photodynamic therapy or photodynamic diagnosis using an illuminator comprising a plurality of light sources generally conforming to a contoured surface and irradiating the

contoured surface with substantially uniform intensity visible light." *Id.*, Abstract.

The specification's description of the invention, according to Biofrontera, presents all three types of the evidence that courts have found sufficient to establish disavowal. First, Biofrontera notes that the asserted patents consistently describe the *present invention* as an illuminator conforming to a contoured surface. *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015) ("We have found disavowal or disclaimer based on clear and unmistakable statements by the patentee that limit the claims, such as 'the present invention includes . . .' or 'the present invention is . . .' or 'all embodiments of the present invention are . . . .').

- "In accomplishing the foregoing objects, there has been *provided according to the present invention* an illuminator for PDT or PD of a contoured surface. The illuminator comprises a plurality of light sources generally conforming to the contoured surface and irradiating the contoured surface with substantially uniform intensity visible light, and a housing supporting the plurality of light sources with respect to the contoured surface." '289 patent, col. 2, l. 66 - col. 3, l. 6 (emphasis added).

- "In accomplishing the foregoing objects, there is also *provided according to the present invention* a method of PDT or PD of a contoured surface. The method comprises topically applying 5-aminolevulinic acid to the contoured surface, and irradiating the contoured surface with substantially uniform intensity visible light from the plurality of light sources generally conforming to the contoured surface." *Id.*, col. 3, ll. 7-13 (emphasis added).

- "In accomplishing the foregoing objects, there is also *provided according to the present invention* for photodynamically diagnosing or treating a contoured surface, the light coming from a plurality of sources generally conforming to the contoured surface and irradiating the contoured surface with uniform intensity." *Id.*, col. 4, ll. 1-6 (emphasis added).

- "*[T]he present invention uses* a U-shaped emitting surface that more closely follows the contours of the human face and scalp." *Id.*, col. 4, ll. 40-42 (emphasis added).

Second, Biofrontera points out that a contoured illuminator is the only embodiment disclosed in the patents, and the patents tie the touted and claimed light output uniformity to this embodiment. *See Andersen Corp. v. Fiber Composites, LLC,* 474 F.3d 1361, 1367 (Fed. Cir. 2007) (limiting "composite compositions" to pellet and linear extrudate forms disclosed in the single embodiment because they are "are essential features of the claimed composite composition"). Both asserted patents claim specific light output thresholds, *see, e.g.*, '289 patent, claim 1 ("at least 60% of the measured maximum over all operation distances"); '991 patent, claim 2 ("within 70% of a measured maximum at distances of 4'' and 2''"). Notably, the specification's only description of meeting these performance benchmarks is attributed to the contoured embodiment. *See* '289 patent, col. 15, ll. 6-11 ("It has been found that, according to a preferred embodiment of the present invention, the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector

at distances of 4'' and 2'', and within 60% of the measured maximum over all operation distances.").

Finally, Biofrontera observes that the asserted patents disparage flat illuminators as being unable to provide the desired uniform light output. *See Pacing Techs.*, 677 F.3d at 1025-1026 ("We also have found disclaimer when the patent repeatedly disparaged an embodiment as 'antiquated,' having 'inherent inadequacies,' and then detailed the 'deficiencies [that] make it difficult' to use."), citing *Chi. Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1372 (Fed. Cir. 2012). "A flat emitting surface would not deliver a uniform light dose to all contours of the face simultaneously because the non-planar facial and scalp surfaces could not be placed at a constant distance from the emitting surface." '289 patent, col. 4, ll. 35-39. According to Biofrontera, each of these factors individually supports a finding of disavowal, while collectively, they compel this conclusion. *See Rembrandt Patent Innovations, LLC v. Apple, Inc.*, 716 F. App'x 965, 971-974 (Fed. Cir. 2017) (affirming the district court's claim construction that while not s0-claimed, computer recovery process was necessarily automated because patent repeatedly characterized recovery process as being automated, single embodiment incorporated and touted the benefits of

automated recovery, and patent disparaged prior art recovery procedures that required human interaction).

While Biofrontera's arguments have substantial weight, the court agrees with DUSA that there is sufficient evidence to the contrary such that, in the totality, Biofrontera falls short of the "exacting" standard for a finding of disavowal. DUSA notes that while an objective of the patents is to more uniformly illuminate a contoured surface, another is to "to provide an improved illuminator for PDT and/or PD" without limitations as to the illuminator's shape. '289 patent, col. 2, ll. 42-43. In addition to distance, the asserted patents identify other factors contributing to output variance in conventional illuminators and offer other techniques for amelioration. For example,

> [t]he present invention differs from conventional light sources because of the biological requirements imposed on a PDT light source. A much higher degree of precision and integration is required for the components of the present invention. Output spectrum, irradiance, and irradiance uniformity all must be controlled to assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction.

Id., col. 4, ll. 17-25. Because "temperature distribution also plays a key role in irradiance uniformity," *id.*, col. 4, ll. 45-46, the patents describe a cooling system that includes vents, a reflector, housing, and fans. *Id.*, col. 9, ll. 5-46. The patents also disclose a controller for automatically adjusting ballast

voltage to the light tubes in response to input from sensors detecting the light output.[6] *See id.*, col. 10, ll. 53-63. "The active switching system is able to correct for changes in power output due to line voltage and temperature variation during treatment; thus external line voltage stabilization is not required according to preferred embodiments of the present invention having automatic adjustment of the ballast voltage." *Id.*, col. 10, l. 63 - col. 11, l. 1. None of these features are tied to any particular shape for the illuminator.

DUSA also rebuts each category of evidence identified by Biofrontera. With respect to illuminator shape, the phrase repeatedly quoted by Biofrontera – "provid[ing a contoured illuminator] according to the present invention" – suggests that a contoured illuminator is consistent with the present invention, but not that it is necessarily a requirement of the invention as a whole. *See TQ Delta, LLC v. Adtran, Inc.*, 2018 WL 2002481, at *3 (D. Del. Apr. 27, 2018) (characterizing "there has been provided in accordance with the present invention" as "permissive language"). Elsewhere in the patent, the language used to describe the same feature is explicitly permissive.

[6] Indeed, claim 1 of the '991 patent is directed to an illuminator with such a controller.

- "The light sources *may* comprise generally U-shaped fluorescent tubes that are driven by electronic ballasts." '289 patent, Abstract (emphasis added).

- "According to *one preferred embodiment* illustrated in FIGS. 1-8, seven U-shaped fluorescent tubes 10(1)-10(7) are driven by three electronic ballasts 20." *Id.*, col. 5, ll. 27-29 (emphasis added).

- "*[O]ne embodiment* of the present invention utilizes a plurality of U-shaped tubes 10(1)-10(7)." *Id.*, col. 6, ll. 16-18 (emphasis added).

At the claim construction hearing, DUSA pointed out that the single instance where the specification directly characterizes "the present invention" as contoured is limited to illuminating the human face and scalp. *See* '289 patent, col. 4, ll. 40-42 ("[T]he present invention uses a U-shaped emitting surface that more closely follows the contours of the human face and scalp."). Likewise, a flat illuminator is also characterized as inadequate in the specific context of application to the face or scalp. *See id.*, col. 4, ll. 35-39 ("A flat emitting surface would not deliver a uniform light dose to all contours of the face simultaneously because the non-planar facial and scalp surfaces could not be placed at a constant distance from the emitting surface."). The invention, however, as DUSA noted, is not limited to cranial applications. *See id.*, col. 1, ll. 26-29 ("The present invention is also directed to an apparatus and method for PDT and PD of other indications (e.g., acne) and *other areas of the patient (e.g., arms, legs, etc.)*.") (emphasis added). A

flat illuminator may well be more appropriate for application to areas of the patient such as the back.

In addition, DUSA identifies another embodiment described in the specification that covers a non-contoured illuminator.

> In accomplishing the foregoing objects, there is also provided according to the present invention an illuminator for emulating an infinite plane emitter. The illuminator comprises an emitting area having a perimeter, and a plurality of light sources being generally parallel to one another, said plurality of light sources being adapted for irradiating substantially uniform intensity light from said emitting area. Lateral spacing between adjacent ones of said plurality of light sources varies with respect to said perimeter.

Id., col. 3, ll. 35-44. In this variation, an illuminator is described physically as having a perimeter and having a plurality of parallel light sources, without requiring that they be contoured.[7] *See Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276 (Fed. Cir. 2008) ("We normally do not interpret claim terms in a way that excludes embodiments disclosed in the specification.")

Finally, DUSA notes that other patents in the same family set out claims explicitly directed to the contoured illuminators. Claim 1 of U.S.

[7] Biofrontera argues that this embodiment is consistent with its construction requiring conformity to a contoured surface because, in the contoured embodiment, the light sources are similarly arranged in parallel. *See id.* Fig. 2 (depicting parallel arrangement of U-shaped light tubes). However, this alternative embodiment is described without any limitation to the overall shape, and is also consistent with a flat illuminator.

Patent No. 6,223,071 (the '071 patent) is directed to "[a]n illuminator for . . . a contoured surface, the illuminator comprising: a plurality of light sources generally conforming to the contoured surface." Likewise, claim 1 of U.S. Patent No. 6,709,446 (the '446 patent) discloses "[a]n illuminator . . . comprising: an array of light sources . . . having a cross-section including an arc-shaped portion and configured to conform to a portion of a patient . . . ." "[W]e presume, unless otherwise compelled, that the same claim term in . . . related patents carries the same construed meaning." *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003). The '071 and '446 patents share the same specification as the asserted patents, and use the same term – "illuminator" – consistently across the family of patents. DUSA contends, and the court agrees, that construing illuminator as necessarily contoured would result in a redundant and unnatural reading of the related patents.[8] For the foregoing reasons, the court will adopt DUSA's proposal and construe "illuminator" as "a light emitting medical instrument."

[8] In opposition, Biofrontera argues that "[d]ifferently worded but similar claims in related patents can be construed identically, especially where those patents share a specification and other technical details." *Shire LLC v. Abhai, LLC*, 219 F. Supp. 3d 241, 246 (D. Mass. 2016). This principle is inapposite in these circumstances. Here, it is the same claim term that appears in related patents supported by the same specification. And nothing in the specification compels a different reading of the term across the patents.

"all operation distances"

The term "all operation distances" appears in claim 1 of the '289 patent. DUSA insists that "all operation distances" should be accorded its plain and ordinary meaning, while Biofrontera asserts that the term is indefinite. Paragraph 2 of 35 U.S.C. § 112 states that a patent's specification "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention." The Supreme Court has interpreted this to "require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable." *Nautilus*, 572 U.S. 898 at 910. Biofrontera must prove indefiniteness, like other grounds of invalidity, by clear and convincing evidence.

According to Biofrontera, a person of ordinary skill in the art would not understand "all operation distances" with reasonable clarity because the specification does not provide any definition or guidance for the term. For its part, DUSA contends that a person of ordinary skill, having experience in photodynamic therapy, would understand the term to refer to the "range of distances at which the PDT device is operated in order to deliver therapy to

a patient." DUSA Br. at 11, citing Zamenhof Decl. (Dkt #74) ¶¶ 36-40.[9] Neither DUSA nor Dr. Zamenhof provides an actual range, and suggests that such may be found in an illuminator's technical manuals. Biofrontera, relying on attorney argument alone, submits that the actual range used by physicians in performing PTD may differ from that specified in the manuals, and such uncertainty leads to a conclusion of indefiniteness.

The court finds that the asserted patents reasonably clearly set out the operational range of an illuminator. The patents identify 2'' and 4'' as the only specific operation distances at which maximum output is to be measured. *See* '289 patent, col. 15, ll. 6-11. It follows, therefore, that the "all operation distances" are "the range of distances between 2'' and 4''."[10]

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[9] Dr. Robert Zamenhof is DUSA's expert witness, and claims "approximately 40 years of experience in the field of medical physics with particular experience in the field of radiotherapy, a form of therapy using ionizing radiation that has many similarities to photodynamic therapy." Zamenhof Decl. ¶ 7.

[10] At the claim construction hearing, DUSA indicated acceptance of this construction. Biofrontera objected because claim 16 of the '289 patent specifies measuring maximums at "distances between 4'' and 2''." Under the principle of claim differentiation, according to Biofrontera, "all operation distances" is necessarily broader. "However, the doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence." *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998). Here, where the only disclosed

"uniform output of light"

The term "uniform output of light" appears in claim 1 of the '991 patent. DUSA contends that this term means "output of light sufficient to activate a target photosensitizer," while Biofrontera again raises the indefiniteness flag. As a threshold matter, the court agrees with Biofrontera that while uniform light output in the activation spectrum of a particular target photosensitizer more effectively and efficiently activates the photosensitizer, *see* '289 patent, col. 2, ll. 30-33 ("it is highly desirable to have an illuminator with a spectral output that overlaps to a large extent with the optical activation spectrum of the target photosensitizer"), the patents do not link "uniform output of light" to activation sufficiency. Rather, the concept of light output uniformity refers to the evenness of the light output. For example, the patents' description of a cooling system for temperature modulation is intended to ameliorate the fact that "the output of tubular light sources may vary with temperature." *Id.*, col. 4, ll. 44-45. Similarly, a function of the automatic controller is to maintain the irradiance output between a minimum and a maximum limit. *See id.*, col. 14, ll. 4-23 (preferred

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operation distances are 2'' and 4'', they will serve to limn the range for "all operation distances."

embodiment has stored operational minimum and maximum regulation limits of 9.3 and 10.7 mW/cm^2).

Rejection of DUSA's proposed construction, however, does not automatically lead to the conclusion that "uniform output of light" is indefinite. Here, too, the court finds that the specification is reasonably clear as to the term's scope. "For therapeutic reasons it is desirable to have a power output which is uniform in intensity and color." *Id.*, col. 2, ll. 24-33. The color of the light output is a function of the specific phosphor used in the florescent tubes. *See id.*, col. 6, ll. 60-63. Intensity, or irradiation, can vary with distance, temperature, and voltage. The latter is what is modulated by the controller claimed in claim 1 of the '991 patent. *See id.*, col. 14, ll. 4-23 (preferred embodiment has stored operational minimum and maximum irradiance limits). The specification and claims are also clear that uniformity is determined as a minimum percentage of the maximum measured at operation distances: "the measured output over the active emitting area is within 70% of the measured maximum when measured with a cosine response detector at distances of 4'' and 2'', and within 60% of the measured maximum over all operation distances." *Id.*, col. 15, ll. 7-11. Because 60% of the measured maximum is the floor of acceptable uniformity disclosed in the patents, the court will construe "uniform output of light" as "the measured

irradiance of light over the active emitting area is at least within 60% of the measured maximum."

ORDER

The disputed claim terms will be construed for the jury and for all other purposes in the pending litigation in a manner consistent with the above rulings of the court.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE